NATIONAL INSTITUTES OF HEALTH
CLINICAL CENTER
NURSING and PATIENT CARE SERVICES

SOP: Care of the Patient Receiving a Controlled Substance Infusion

Essential Information:

1. A controlled substance infusion administered by an invasive route (e.g., intravenous, subcutaneous, epidural, epineural) is categorized as a high-alert drug and as such, is subject to the conditions described in the SOP: Medication Administration.
2. Patient Identification – for patient safety and to accurately identify the "*right patient*," a nurse compares the patient identification band against hospital records and/or hospital-generated labels. Alternatively, if the patient does not have an identification band, a nurse will ask the patient or parent/guardian to state the patient's full name and date of birth (MAS M03-1: Patient Identification).
3. Two (2) independent checks of a high alert drug is defined as 2 licensed health care professionals who each separately**:**
   a. Compare the nursing **process** of preparing a drug product for administration (e.g., IV admixtures, injections, etc.) against the medical order for the right patient, drug, concentration, dose, administration route, diluent and volume, if appropriate, date and time of administration, and product expiration dating.
   b. Compare all **drug product labels** (CC-generated drug product label and manufacturer's drug product label, if present) against the medical order for the right patient, drug, dose, concentration, route, date and time of administration, and product expiration dating.
   c. Compare the **infusion pump settings** (which may include the volume to be infused, the drug, concentration, basal rate, bolus dose, lockout intervals, dose limits, and range settings) against the medical order.
   d. Review the **ordered route of infusion** and check the line attachment by tracing from the drug product along the administration set to the site of infusion.
   e. Carry out any required **drug calculation** and compare it against the medical order.
4. The Department of Anesthesia manages all epidural and epineural infusions of controlled substances including dressing changes at epidural catheter insertion sites.
5. The Pharmacy prepares all controlled substance infusions containing multiple doses or for continuous infusion, in accordance with POL: Parenteral Admixtures.

I. ASSESSMENT

A. Prior to initiation of any controlled substance infusion, a nurse:
   1. Reviews prior medical orders for analgesics and sedatives.
   2. Assesses the integrity of infusion route, e.g. intravenous or epidural catheter, subcutaneous site

B. With the initiation of a controlled substance infusion or dosage increase, a nurse assesses the following every 30 minutes X2:
   1. Pain location and intensity
   2. Blood pressure, respiratory rate, oxygen saturation
   3. Level of sedation

C. A nurse assesses the following at least every 4 hours:
   1. Pain location and intensity
   2. Blood pressure, respiratory rate, oxygen saturation

3. Level of sedation
4. Infusion pump settings which may include drug, drug concentration, basal rate, bolus dose, lockout interval, dose limit, and total hourly dose.
5. Total amount administered including number of PCA doses given and attempted.
6. Adverse reactions which may include nausea/vomiting, bowel and urinary bladder dysfunction, rash, pruritis, motor strength, and visual disturbances.

D. Two (2) independent checks of the drug product label, the infusion pump settings and the infusion route are performed and:
1. Prior to the initiation of a controlled substance infusion
2. With each bag change
3. With any change in infusion pump settings including clinician activated bolus
4. With a change in caregiver

E. For **epidural infusion**, a nurse additionally assesses the following at least every 4 hours:
1. Integrity of dressing over insertion site.
2. Epidural catheter is intact and all connections are secured with tape without visible kinks.
3. Motor and sensory responses

F. For **subcutaneous infusion**, assess the following prior to initiation and then every 4 hours:
1. Insertion site for proper depth of catheter or needle
2. Edema and/or infection at site of needle insertion
3. Discharge and/or leaking fluids

G. Prior to termination of analgesic infusion, a nurse:
1. Assesses the patient's readiness to decrease, discontinue or change mode of delivery of analgesia
2. Reviews medical orders for alternative pain interventions.

H. Post-termination, a nurse reassesses pain intensity and location when the analgesic effect might be expected to be diminished.

II. INTERVENTIONS

A. A controlled substance infusion is delivered by an approved flow-controlled infusion pump.

B. An appropriate program lock and/or container lock are used to secure the pump settings.

C. A controlled substance solution is initiated prior to the product's expiration date and is:
1. Changed every 24 hours unless otherwise specified by treatment protocols or medical order.
2. Labeled with date/time started and nurse's initials.

D. Infusion administration sets are changed at least every 72 hours.

E. Naloxone HCl (Narcan®) is readily available in patient care area. Patients receiving parenteral opiates should have a medical order for Naloxone HCl.

F. Administration sets specifically approved for an epidural infusion are used and are additionally labeled to identify the epidural route.

G. For **subcutaneous infusion:**
1. Subcutaneous sites that show no evidence of irritation or infection are used as sites of infusion.
2. Insertion site is rotated every 3 days or whenever there is evidence of edema, pain, infiltration, redness, or infusion resistance.
3. Subcutaneous infusion sites are protected from injury by securing tubing and connections using tape and/or other approved protective devices.

H. Patient/family is instructed in accordance with the SOP: Medication Administration and also:

1. To contact nurse with questions or concerns about pain management
2. For PCA users only:
   a. Explain the concept of Patient Controlled Analgesia (PCA)
   b. Observe patient pushing patient dose button to assess ability to push button
   c. Reinforce need for patient to participate actively in managing PCA
   d. Instruct family members that they should not push the patient dose button
3. When a controlled substance infusion is terminated, a nurse instructs the pt/family in the:
   a. Rationale for termination of infusion and the plan for continued pain management.
   b. Need to report any increase in pain level to a nurse.

III. DOCUMENTATION

A. In general, the following documentation guidelines apply to the Patient Controlled Analgesia Flowsheet, Form NIH-2804 (3-02) (PCA Flowsheet):
   1. A PCA Flowsheet is initiated whenever PCA is initiated or there is a change in the drug and/or the drug concentration
   2. Two (2) RNs record their signatures validating the independent check process
   3. One (1) RN signature every 4 hours to indicate who reviewed and recorded the pump settings
   4. Infusion rate changes and bag changes are documented

B. **On the PCA Flowsheet**, a nurse documents at least every 4 hours:
   1. Programmed pump settings
   2. Number of patient-initiated boluses given and attempted, basal dosage given, total dosage given, and clinician-activated boluses.
   3. Level of Sedation
   4. Pain Intensity and pain intensity instrument used
   5. Vital signs

C. **In the approved electronic record**, the nurse documents
   1. at least every 4 hours:
      a. Pain reassessment
      b. Vital signs
      c. Motor and sensory assessment (epidural only)
   2. the start and end time of the controlled substance infusion.

IV. REFERENCES

A. NIH Clinical Center Nursing Department Policy: Handling of Controlled Substances
B. Naber, L, Jones, G., & Halm, M. (1994). Epidural Analgesia for Effective Pain Control. Critical Care Nurse, 10, 69-84.
C. Smythe, M. (1992). Patient Controlled Analgesia: A Review, Pharmacotherapy, 12(2), 132-143.
D. Stanik, JA (1991). Use of patient controlled analgesia with critically ill patients: a risk/benefit analysis. AACN, 2(4), 741-747.
E. SOP: Care of the Patient with Actual or Potential for Pain (June 2003)

Approved:

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